IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, LLC,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 09-161-LPS
	:	
INTERVET, INC., d/b/a INTERVET/SCHERING-PLOUGH ANIMAL HEALTH,	:	
	:	
Defendant.	:	

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MEMORANDUM OPINION

March 22, 2011
Wilmington, Delaware.

Stark, District Judge:

Plaintiff, Wyeth, LLC ("Wyeth"), filed this patent infringement action against Defendants, Intervet, Inc. ("Intervet") and Boehringer Ingelheim Vetmedica Inc. ("Vetmedica"), on March 12, 2009. (D.I. 1) Vetmedica was dismissed on July 13, 2010. (D.I. 125) Wyeth alleges that Intervet infringes seven of its patents related to porcine circovirus vaccines: U.S. Patent No. 6,703,023 (the "'023 patent"),[1] U.S. Patent No. 7,223,407 (the "'407 patent"),[2] U.S. Patent No. 7,223,594 (the "'594 patent"),[3] U.S. Patent No. 7,407,803 (the "'803 patent"),[4] U.S. Patent No. 7,604,808 (the "'808 patent"),[5] U.S. Patent No. 7,772,883 (the "'883 patent"),[6] and U.S. Patent No. 7,740,886 (the "'886 patent")[7] (collectively, the "patents-in-suit"). (D.I. 1) Intervet filed counterclaims seeking declaratory judgments that Intervet's accused product does not infringe the asserted claims and the asserted claims are invalid. (D.I. 14) Presently before the Court is the matter of claim construction.

I. BACKGROUND

A. Procedural Background

Briefing on claim construction was completed on October 29, 2010. (D.I. 159; D.I. 160;

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[1]The '023 patent is found at D.I. 160 Ex. A. The specifications of each of the seven patents-in-suit are essentially identical.

[2]The cover sheet and claims of the '407 patent are found at D.I. 160 Ex. B.

[3]The cover sheet and claims of the '594 patent are found at D.I. 160 Ex. C.

[4]The cover sheet and claims of the '803 patent are found at D.I. 160 Ex. D.

[5]The cover sheet and claims of the '808 patent are found at D.I. 160 Ex. E.

[6]The cover sheet and claims of the '883 patent are found at D.I. 160 Ex. F.

[7]The cover sheet and claims of the '886 patent are found at D.I. 160 Ex. G.

D.I. 169; D.I. 171) The Court held a *Markman* hearing on November 9, 2010. *See* Claim Construction Hr'g Tr., November 9, 2010 (D.I. 180) (hereinafter "Tr.").

B. The Patents-In-Suit

The patents-in-suit are directed to vaccines, vaccine components, and recombinant DNA techniques for making vaccines that protect livestock pigs from a viral disease referred to in the patents-in-suit as Piglet Wasting Disease ("PWD"). The same disease is also known as Post-Weaning Multisystemic Wasting Syndrome ("PMWS") and Fatal Piglet Wasting ("FPW"). Porcine circoviruses – viruses containing circular single-stranded DNA – have been associated with PWD. The patents-in-suit issued in 2004 (the '023 patent), 2007 (the '407 and '594 patents), 2008 (the '803 patent), 2009 (the '808 patent), and 2010 (the '866 and '883 patents). They all stem from a French patent application filed on December 5, 1997 and, therefore, share a common specification. The claims were divided among the seven patents-in-suit pursuant to a restriction requirement issued by a U.S. Patent and Trademark Office ("PTO") Examiner during prosecution of the initial U.S. application.

C. The Asserted Claims

Wyeth asserts ninety claims against Intervet. (D.I. 159 Ex. C) They are: claims 1, 3, 5, and 7 from the '023 patent; claims 1-2, 5-6, 9-10, 13-14, 17, 21-23, and 27-28 of the '407 patent; claims 1-2, 5-6, 9-10, 13-14, 17-19, 23-25, 28, 35-36, 39-40, 43-44, and 47-48 of the '594 patent; claims 1-4 and 11-15 of the '803 patent; claims 1, 4, 7-20, 23-24, and 27-30 of the '808 patent; claims 10 and 16 of the '883 patent; and, finally, claims 30-31, 34, 37, 43-46, 48-52, 56-57, and 60 of the '886 patent.

D. The Disputed Terms

The parties present three disputed terms. The first is actually a group of five terms that the parties agree have the same meaning. The five grouped terms are: "porcine circovirus type B," "PCVB," "type B porcine circovirus," "porcine circovirus-B," and "PCV-B" (collectively "PCVB"). These terms appear in thirty-one asserted claims.[8] (*See* D.I. 159 Ex. B)

The second disputed term is actually the whole of claim 1 of the '023 patent. As discussed below, Intervet's proposed construction reveals that three terms in claim 1 are really in dispute: "vaccine," "nucleic acid," and "encoding."

The final disputed term is "amplifying said nucleic acid," which appears only in claim 25 of the '594 patent.

A representative claim containing the term PCVB is reproduced below, along with claim 1 of the '023 patent and claim 25 of the '594 patent. The disputed terms are highlighted.

> A method for treating or preventing ***porcine circovirus type B*** infection in a mammalian subject, comprising administering to said subject a therapeutically effective amount of a vaccine according to claim 5.

('407 patent, claim 13)

> A ***vaccine*** comprising a ***nucleic acid*** having a nucleotide sequence with at least 90% sequence identity to SEQ ID No. 25 and an acceptable pharmaceutical vehicle, wherein said nucleic acid ***encodes*** an immunogenic protein that induces a protective response effective against infection by a piglet weight loss disease circovirus.

('023 patent, claim 1)

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[8]They are: claims 13-14, 21-23, and 27-28 of the '407 patent; claims 13-14, 17-19, 23-25, 28, and 47-48 of the '594 patent; claims 1-4 and 11-15 of the '803 patent; claims 19 and 30 of the '808 patent; and claims 10 and 16 of the '883 patent.

> The method of claim 23, said method further including the step of ***amplifying said nucleic acid*** from a strain of PCVB prior to cloning said nucleic acid into said transfer vector.

('594 patent, claim 25)

II. LEGAL STANDARDS

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). Construing the claims of a patent presents a question of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered.

Phillips, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . ." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff'd*, 481 F.3d 1371 (Fed. Cir. 2007).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980. The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent."

Phillips, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

A court also may rely on "extrinsic evidence," which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of ordinary skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful" to the court, it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19.

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct

interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007). Thus, if possible, claims should be construed to uphold validity. *See In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984).

III. CONSTRUCTION OF DISPUTED TERMS

A. "PCVB"

Wyeth argues that PCVB is a broad term meaning "a pathogenic porcine circovirus associated with piglet weight loss disease." Wyeth, therefore, asserts that this term refers to a category of viruses encompassing any porcine circovirus that "causes the disease conditions and clinical symptoms associated with PWD."[9] (D.I. 160 at 9) By contrast, Intervet argues for a narrow construction, proposing "a porcine circovirus having the genomic sequence of SEQ ID No. 15 or SEQ ID No. 19." Intervet, therefore, contends that the disputed term refers to one specific porcine circovirus, not a group of viruses.

The parties agree that five terms – porcine circovirus type B, PCVB, type B porcine circovirus, porcine circovirus-B, and PCV-B – are used interchangeably throughout the claims and have the same meaning. But inspection of the claims reveals further variety in how these terms are used (e.g., as an adjective or noun, with or without a preceding article), as well as the use of similar terms that, evidently, the parties believe have different meanings. The disputed terms (with emphasis added) appear in the asserted claims in the following ways:

> "A method for treating or preventing ***porcine circovirus type B infection*** in a mammalian subject . . ." ('407 patent, claims 13-14; '594 patent, claims 13-14, 47-48)

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[9]Although Wyeth's proposed construction uses the singular form "circovirus," the use of the indefinite article "a" preceding the word "circovirus" means that, under Wyeth's construction, any virus associated with PWD satisfies the limitation. (Tr. 11)

"A method for expressing ***ORF'2 of a porcine circovirus type B (PCVB)*** . . ." ('407 patent, claims 21-22, 27)

"A method of recovering protein expressed by ***ORF'2 from PCVB*** . . ." ('594 patent, claim 17)

"A method for preparing a composition for inducing an immune response against ***PCVB*** . . ." ('594 patent, claim 23)

". . . including the step of amplifying said nucleic acid from ***a strain of PCVB*** prior to cloning . . ." ('594 patent, claim 25)

"a ***porcine circovirus type B antigen or epitope*** thereof . . ." ('803 patent, claim 1)

". . . wherein the composition induces an immune response in a porcine host against ***type B porcine circovirus***" ('803 patent, claim 4)

". . . wherein the vector is capable of inducing an immunogenic reaction in a porcine host against ***a type B porcine circovirus***" ('803 patent, claims 13, 30)

". . . wherein ***the PCVB antigen*** is encoded by a sequence . . ." ('803 patent, claim 15)

". . . wherein the polypeptide induces an immunological response in a porcine against ***PCVB***" ('883 patent, claim 10)

The following terms, which are similar to the disputed terms, appear in the claims as well (emphasis added):

". . . wherein said nucleic acid sequence encodes an immunogenic protein that induces a protective response effective against infection by ***a piglet weight loss disease virus***" ('407 patent, claims 5-8; '594 patent claims 5-8)

"A method for inducing an immunological response against ***a porcine circovirus*** comprising . . ." ('803 patent, claim 12)

". . . wherein said nucleic acid encodes an immunogenic protein

> that induces a protective response effective against infection by ***a piglet weight loss disease circovirus*** . . ." ('883 patent, claims 1-4)

The claim language, therefore, distinguishes between PCVB and "a piglet weight loss disease circovirus," with the latter seeming to be a more general term.

Claim 13 of the '407 patent further illustrates this distinction. This claim is dependent on claim 5, which in turn depends on claim 1. Claim 13, with the language of claims 1 and 5 inserted, and emphasis added, states:

> A method for treating or preventing ***porcine circovirus type B*** infection in a mammalian subject, comprising
>
> > administering to said subject a therapeutically effective amount of [a] vaccine composition, comprising
> >
> > > [a] vector capable of expressing at least one polypeptide encoded by a nucleic acid sequence comprising a sequence having at least 90% sequence identity to SEQ. ID. NO: 25 and
> >
> > > a pharmaceutically or veterinarily acceptable carrier,
> >
> > > wherein said nucleic acid sequence encodes an immunogenic protein that induces a protective response effective against infection by ***a piglet weight loss disease virus***.

Claim 13, hence, uses both terms: "porcine circovirus type B" and "a piglet weight loss disease virus." This suggests, again, that "porcine circovirus type B" has a different meaning than "a piglet weight loss disease virus."

The specification also sheds light on the distinction between these two terms. The term

"PWD circovirus" is described in the detailed description of the invention as follows:

> In the present description, PWD circovirus will be understood as designating the circoviruses associated with piglet weight loss disease (PWD) of type A (PCVA) or type B (PCVB), defined below by their genomic sequence, as well as the circoviruses whose nucleic sequences are homologous to the sequences of PWD circoviruses of type A or B, such as in particular the circoviruses corresponding to variants of the type A or of the type B.

('023 patent, col. 8 lines 11-18) The specification, therefore, identifies a broad category of viruses (PWD circovirus) and four sub-categories encompassed within this broad category (PCVA, PCVB, sequences homologous[10] to PCVA, and sequences homologous to PCVB).

Other portions of the specification make clear that "PWD circovirus" is a category that includes PCVB. When discussing the problem addressed by the patented invention, the specification indicates that the invention is used to distinguish between strains of PWD circovirus. (*Id.* col. 3 lines 13-15) ("A reliable, sensitive and practical test which allows the distinction between strains of porcine circovirus (PCV) is thus strongly desirable.") One of these strains is PCVB. (*Id.* col. 31 lines 62-63) ("The other type of virus is a circovirus and is associated with FPW. This circovirus, of which two types have been isolated and sequenced, designated below PWD circovirus type A (or PCVA) and PWD circovirus of type B (or PCVB),

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[10]Sequences that are homologous are genetically similar to each other. ('023 patent, col. 7 lines 23-25) ("The term 'degree of percentage of sequence homology' refers to 'degree or percentage of sequence identity between two sequences after optimal alignment.'") The measure of homology, or similarity, is referred to as "sequence" or "percentage identity." (*Id.* col. 7 lines 1-8) ("Homologous nucleotide sequence in the sense of the present invention is understood as meaning a nucleotide sequence having at least a percentage identity with the bases of a nucleotide sequence according to the invention of at least 80%, preferably 90% or 95%, this percentage being purely statistical and it being possible to distribute the difference between the two nucleotide sequences at random and over the whole of their length.") The similarities usually arise because the homologous sequences derive from the same source. (Tr. 46) (Wyeth stating that "[a] homologue can be anything that is derived from the same original source.")

have mutations with respect to the known sequences of circovirus which are nonpathogenic for the pig."); (*id.* col. 45 lines 61-64) ("These membranes were used for immunoreactivity tests with respect to serum of SPF pigs which were or were not infected experimentally with ***the type B PWD circoviral strain***.") (emphasis added); (*id.* col. 47 lines 27-28) ("PCV-B ORF'1 and ORF'2 genes, isolated from ***PCV-B challenge strain***, have been cloned into vector plasmid pcDNA3.1.") (emphasis added)

The claim language and specification, therefore, indicate that PCVB has a different and narrower meaning than PWD circovirus; that is, PCVB is a type of PWD circovirus. (*See, e.g., id.* col. 24 lines 47-48) ("[O]ne of the two said compounds is related to the PWD circovirus of type A, and the other is related to the PWD circovirus of type B.") Since Wyeth's proposed construction of the narrower term PCVB ("the term PCVB . . . means a pathogenic porcine circovirus associated with piglet weight loss disease") is almost identical to the definition of the broader term PWD circovirus given in the specification ("the circoviruses associated with piglet weight loss disease"), Wyeth's construction must be wrong.

Moreover, the specification states that PCVB is "defined below by [its] genomic sequence." (*Id.* col. 8 lines 13-14) Elsewhere, the specification describes the experiment in which PCVB was cloned, sequenced, and characterized, labeled "Example 2." (*Id.* col. 34 line 48 to col. 35 line 6) There, the specification states:

> The nucleic acid sequence of the (+) polarity of the genome of PWD circovirus type B (or PCVB) is represented by the sequence SEQ ID No. 15 in the sequence listing, the nucleic sequence of the strand of (–) polarity of the genome of the PWD circovirus of type B (or PCVB) being represented by . . . the sequence SEQ ID No. 19 . . . in the sequence listing.

(*Id.* col. 34 lines 57-64) These are the defining sequences referred to earlier in the specification; in this way, the inventor defined the term PCVB with SEQ ID No. 15 and 19. *See Phillips*, 415 F.3d at 1316 ("[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs."); *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1318 (Fed. Cir. 2005) ("A patentee may define a particular term in a particular way, and in that event the term will be defined in that fashion for purposes of that particular patent, no matter what its meaning in other contexts."). Further, the use of the definite article in "the genome of PWD circovirus type B" indicates that one genome is contemplated and, hence, only one virus – not a group of viruses – is referred to by the term PCVB. SEQ ID No. 15 and 19 are this one genome.[11] The Court, therefore, construes "PCVB" as "a porcine circovirus having the genomic sequence of SEQ ID No. 15 or SEQ ID No. 19."

Wyeth argues that limiting the term PCVB to two nucleotide sequences, which are complements of each other, renders the pertinent claims nonsensical. (D.I. 160 at 10) For example, Wyeth points to claim 23 of the '594 patent, which contains the term PCVB in its preamble. The preamble states the claim is directed to "a method of preparing a composition for

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[11]The cited portion of the specification states that the genome of PCVB is "represented by" SEQ ID No. 15 and 19, but the Court does not interpret this to mean that these sequences are merely "representative of" the genome (i.e., that other representative sequences exist). Rather, the sequences appear in the specification as a long string of letters (A, C, G, and T), each letter corresponding to a particular base. ('023 patent, col. 85-89, 97-99) This is why they "represent" the genome – the letters represent the bases that make up the genome. In fact, in an earlier portion of the specification, where SEQ ID No. 15 and 19 are first introduced, essentially the same language appears as is quoted above. But there, instead of using the term "represented by," the specification states that SEQ ID No. 15 and 19 "***correspond respectively to*** the genome sequence" of PCVB, emphasizing that these sequences are the genome. ('023 patent, col. 6 lines 5-8) (emphasis added)

inducing an immune response against PCVB," and the first claim element requires 90% sequence identity to SEQ ID No. 25. Inserting Intervet's proposed construction, Wyeth argues, requires an immune response against a virus having the genomic sequence SEQ ID No. 15 or 19, yet the claim would only require 90% sequence identity to SEQ ID No. 25, which corresponds to ORF'2, a portion of SEQ ID No. 15 and 19. The Court finds nothing nonsensical about this result. The claim teaches that a composition effective against a specific viral strain can be made by using a sequence that is 90% identical to a portion of that strain. Even without complete identity, the composition will still protect against the strain.[12]

Wyeth also argues that Intervet's construction frustrates the purpose of the invention, citing claim 13 of the '407 patent. (D.I. 160 at 12) That claim contains a preamble which uses the disputed term: "A method for treating or preventing porcine circovirus type B infection in a mammalian subject, comprising . . . ." Wyeth asserts that this claim, like many others, "is directed to a vaccine that protects pigs from the deleterious effects of PWD." (*Id.*) That is an accurate statement: PCVB causes PWD, the claimed method treats PCVB infection, thus the claimed method treats a cause of PWD. But this does not establish that the purpose of the invention is, as Wyeth asserts, to treat all causes of PWD. The purpose of the claimed method is to treat PCVB infection, and the only way this encompasses treating infections by all PWD circoviruses is if Wyeth's construction is adopted. Wyeth's argument is circular.

Wyeth also contends that the specification establishes that SEQ ID No. 15 and 19 are

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[12]The Court need not decide if the preamble imposes a separate limitation on the claim – preambles typically do not when they only state the purpose or intended use of the claimed invention. *See Symantec Corp. v. Computer Assocs. Int'l*, 522 F.3d 1279, 1288-89 (Fed. Cir. 2008).

"exemplary embodiments of the genome of PCVB." (D.I. 160 at 13) The Court does not agree. Wyeth cites the following language from the specification:

> The present invention relates to vaccines comprising a nucleotide sequence of the genome of Porcine circovirus type B, or a homologue or fragment thereof, and an acceptable pharmaceutical or veterinary vehicle. In one embodiment of the invention, the nucleotide sequence is selected from SEQ ID No. 15, SEQ ID No. 19, SEQ ID No. 23, or SEQ ID No. 25, or a homologue or fragment thereof.

('023 patent, col. 3 lines 41-47) Wyeth also cites the following excerpt:

> The present invention also relates to vaccines comprising a polypeptide encoded by a nucleotide sequence of the genome of PCVB, or a homologue or fragment thereof, and an acceptable pharmaceutical or veterinary vehicle. In one embodiment, the homologue has at least 80% sequence identity to SEQ ID No. 15, SEQ ID No. 19, SEQ ID No. 23 or SEQ ID No. 25. In another embodiment of the invention, the nucleotide sequence is selected from SEQ ID No. 23 or SEQ ID No. 25, or a homologue or fragment thereof.

(*Id.* col. 3 lines 52-58) Both these excerpts describe embodiments of the claimed vaccine, not embodiments of PCVB. Both indicate that SEQ ID No. 15, 19, 23, and 25 are "nucleotide sequence[s] of the genome of PCVB." SEQ ID No. 15 and 19 are complete sequences and each other's complements (i.e., only one sequence is really represented) and SEQ ID No. 23 and 25 are portions (ORFs) of those complete sequences. The specification in no way indicates that other PCVB sequences exist or that these two sequences are merely representative embodiments.

To further argue that the term PCVB includes other variants, Wyeth relies on the specification's definition of homologues or variants of PCVB. But, as described above, when "PWD circovirus" is defined in the specification, a distinction is made between PCVB and its homologues (i.e., they are separate types of PWD circoviruses), contradicting Wyeth's assertion.

Further, the broader coverage Wyeth attempts to introduce through its construction of PCVB – that homologous sequences are included – is already achieved through the sequence identity requirements of the claims. The specification defines homologous sequences as follows:

> Homologous nucleotide sequence in the sense of the present invention is understood as meaning a nucleotide sequence having at least a percentage identity with the bases of a nucleotide sequence according to the invention of at least 80%, preferably 90% or 95%, this percentage being purely statistical and it being possible to distribute the difference between the two nucleotide sequences at random and over the whole of their length.

Wyeth even explains in its brief that the scope of the claims is defined by the sequence identity limitations. (*See* D.I. 169 at 10) ("All such claims also include a separate limitation requiring a nucleotide or amino acid sequence with 90% sequence identity to SEQ ID Nos. 25 or 26. . . . It is those specific sequence limitations that more precisely limit the scope of the claims.")[13] The term PCVB does not include homologues of the disclosed sequences; the two are distinguished in the specification and the claims account for this distinction with sequence identity limitations.

Wyeth's strongest argument against limiting the term PCVB to the two disclosed sequences is based on claim 25 of the '594 patent, which contains the limitation "said method

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[13]Intervet also recognizes this and notes that, even under its construction, the scope of the claims is not limited to vaccine compositions effective only against viruses defined by SEQ ID No. 15 and 19 but, rather, the compositions may be effective against homologues of this virus as well. (*See* D.I. 171 at 7) ("When Intervet's construction is properly read in the context of . . . claims that relate to infection by, or inducing a protective response against 'PCV-B' . . . it requires that the vaccine composition or method of these claims *at least* induce an immune response against the virus defined by the sequences set forth in the specification, i.e., SEQ ID Nos. 15 and 19. . . . Nothing in Intervet's construction prevents a vaccine from being effective against infections by any number of homologous viruses."); (*see also* Tr. 36) (Intervet counsel: "[I]t has to be effective against PCVB as defined in the patent specification, but it can also be effective against any other porcine circovirus. . . . I would say that our construction of PCVB does not limit these claims in any real fashion.")

further including the step of amplifying said nucleic acid from ***a strain of PCVB*** prior to cloning said nucleic acid into said transfer vector" (emphasis added). This language may imply that more than one variant of PCVB exists. But the specification never refers to different strains of PCVB; only strains of PWD circovirus are discussed, with PCVB being one of these strains. (*See, e.g.*, '023 patent, col. 45 lines 61-64; *id.* col. 47 lines 27-28) Still, claim 25 makes it troublesome to construe PCVB as only SEQ ID No. 15 and 19 – since both parties agree these two sequences represent one strain. (Tr. 16, 30) Although the Court has not been asked to construe the term "a strain of PCVB," the Court has tried to make sense of this term to properly construe PCVB – and the Court had trouble doing so. But, at bottom, the Court cannot justify expanding the definition of PCVB beyond the two disclosed sequences based on this single fleeting reference to strains of PCVB. The specification repeatedly defines PCVB with respect to the two sequences SEQ ID No. 15 and 19, and the one reference to "a strain of PCVB" is insufficient to modify that definition.[14] *Cf. Genentech, Inc. v. The Wellcome Found. Ltd.*, 29 F.3d 1555, 1563-65 (Fed. Cir. 1994) (adopting narrowest structural definition of term "human tissue plasminogen activator" where there were "at least four possible definitions" of varying breadth in specification).

Finally, Wyeth cites a recent Federal Circuit case involving Intervet in support of its

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[14]At the *Markman* hearing, Intervet raised a possible explanation for the appearance of the term "a strain of PCVB" in only one place: claim 25 was added late in prosecution, in October of 2006, to allow for the initiation of an interference proceeding. (Tr. 42-43) The claim was copied from the application to be challenged. *See* '594 File History, October 13, 2006 Response to Restriction Requirement at 19 ("Claims 243-264 [note: claim 244 issued as claim 25] have also been added, which are essentially identical to, and were copied from, various Claims 1-53 of WO 2006/072065 A2, published on July 6, 2006 from PCT/US2005/047596 to Eichmeyer et al. . . . Claims 243-264 were added to avoid any question of compliance with 35 U.S.C. § 135(b)(2) should an interference later be desired and/or determined to be appropriate.").

construction. (D.I. 160 at 15) In that case, the Federal Circuit reversed a construction of the term "porcine circovirus type II," which limited the term to four sequences disclosed in the specification. *See Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1288 (Fed. Cir. 2010). The Federal Circuit held that the four sequences were representative of a type of porcine circovirus, and the disputed term referred to the whole category, which included more than just these four sequences; in fact, the patent disclosed five exemplary strains, but only four were sequenced. *Id.* at 1287. The specification at issue in *Merial* contained clear language indicating that the four sequences were representative of a genus. *See* U.S. Patent No. 6,383,601, col. 1 lines 48-62 ("The applicant has succeeded in isolating five new PCV strains. . . . The applicant has, in addition, sequenced the genome of four of these strains. . . . The new strains can thus be considered as being representative of a new type of porcine circovirus, called here type II."). But no such language is present in the specifications of the patents-in-suit. Instead, the description of the two disclosed sequences in the patents-in-suit states that the sequences "***correspond respectively to*** the genome sequence of (+) polarity and of the strand of (–) polarity of the PWD circovirus type B (or PCVB)." ('023 patent, col. 6 lines 5-8) (emphasis added) The quoted language makes clear that PCVB has a specific genome sequence; it is not a category of viruses.

In *Merial*, the Federal Circuit decided on a construction that included variants of the four disclosed sequences: "a pathogenic pig virus having a circular genome that is at about 96% or more homologous with the four sequences disclosed in the present specification, and about 76% or less homologous to PK/15 sequence." 617 F.3d at 1288. The Federal Circuit held that the new type of virus – porcine circovirus type II – was described in the specification by its

"pathogenecity and homology patterns" and, thus, limited the genus to viruses with similar homology to the disclosed strains. *Id.* No such description was provided in the patents-in-suit. Only two sequences were disclosed (SEQ ID No. 15 and SEQ ID No. 19), the specification makes clear these two sequences are complements (which Wyeth does not dispute), and their relationship is not described in terms of homology. In these circumstances, the Court has no means for extending the term PCVB beyond these two sequences.

Therefore, the Court construes PCVB to mean "a porcine circovirus having the genomic sequence of SEQ ID No. 15 and SEQ ID No. 19."

B. Claim 1 of the '023 Patent

Wyeth asserts that claim 1 of the '023 patent needs no construction. (D.I. 160 at 19) Intervet, by contrast, requests that the Court construe claim 1 in its entirety, but not any specific term in the claim. (D.I. 159 at 12) Specifically, Intervet asks that claim 1 of the '023 patent be recast to read:

> A pharmaceutical composition containing a naked DNA having a nucleotide sequence with at least 90% sequence identity to SEQ ID No. 25 and an acceptable pharmaceutical vehicle, wherein the cells of an immunized animal use their machinery to produce a protein from the naked DNA, wherein the protein induces a protective response effective against infection by a piglet weight loss disease circovirus.

(D.I. 159 at 12)[15] Intervet relies on cases requiring that claims be interpreted in context. (D.I. 171 at 14-15) (citing *Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183 F.3d 1369 (Fed. Cir. 1999) and *Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1347 (Fed. Cir 2008))

[15]The actual language of claim 1 of the '023 patent is reproduced above in Section I.D.

The Court finds these cases inapplicable, i.e., they do not require that this claim be construed as a whole when no particular term is disputed.[16] In any event, the Court finds that Intervet essentially requests that "vaccine" be replaced with "pharmaceutical composition," and two limitations be added to the claim: that the vaccine contain "naked DNA" and that there be intracellular production of the protein. The Court finds none of these alterations of the actual claim language to be warranted.

Intervet emphasizes that claim 1 is drawn to a "DNA vaccine" and, thus, requires "naked DNA." (D.I. 159 at 12-14; D.I. 171 at 13) In support of this argument, Intervet primarily relies on the prosecution history, in particular, a restriction requirement imposed by the PTO on April 10, 2002. (D.I. 164 Ex. 8) The Examiner identified five categories of inventions in the original application, one of which was DNA vaccines. (*Id.* at 2) Intervet argues that this restriction requirement and the subsequent election to prosecute the DNA vaccines in the application resulting in the '023 patent (D.I. 164 Ex. 9) should limit the scope of claim 1. Intervet asks the Court to construe claim 1 to exclude any of the unelected inventions. (D.I. 159 at 14)

Intervet's is a prosecution history disclaimer argument. But "for prosecution disclaimer to attach, [Federal Circuit] precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325-26 (Fed. Cir. 2003). Furthermore, "courts have questioned whether it is

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[16]Of course, there are also situations where construing a claim as a whole is proper. *See, e.g., Merial*, 617 F.3d at 1289 ("The parties below could not agree on what terms of claim 32 were disputed, and the district court decided to construe the claim in its entirety. . . . We see no error in this construction.").

appropriate to use a restriction requirement to substantively limit claims." *Laboratoires Perouse, S.A.S. v. W.L. Gore & Assocs., Inc.*, 528 F. Supp. 2d 362, 374 (S.D.N.Y. 2007); *see also Michaels of Or. Co. v. Clean Gun, LLC*, 2002 WL 31496414, at *8 (D. Or. July 9, 2002). The court in *Laboratoires Perouse* found that a "restriction requirement simply requires an applicant to segregate its [claims to two inventions] into separate patent applications. . . . While the [applicant's] election in response to [a] restriction requirement might arguably be viewed as an admission that the elected [first] invention is not an element of the non-elected [second] invention, it did not impose an additional limitation on any claims so as to exclude products that include [both inventions] in combination or physical contiguity." 528 F. Supp. 2d at 375.

This logic applies here. There is no additional limitation in claim 1 excluding a product that is, for example, both a DNA vaccine and a transformed cell vaccine in combination. The election of a species provides no basis for limiting the language of claim 1; it is no clear and unmistakable disavowing statement. *See Michaels of Or.*, 2002 WL 31496414, at *8 (noting that "[r]estriction requirements do not constitute a substantive claim construction doctrine. Instead, restriction practice is a procedural tool that may be implemented when the PTO finds that an applicant has two distinctly patentable inventions in the same application. Unlike a rejection for obviousness or anticipation, the inclusion of two or more inventions in the same application does not render the inventions unpatentable.").

From another perspective, Intervet's proposal is a request to construe three terms present in claim 1: "vaccine," "nucleic acid," and "encodes." The Court is not persuaded that these three

terms require construction.[17] First, "vaccine" is a commonly used word with a well-established plain and ordinary meaning, and nothing in the specification indicates that the patentee intended a different meaning. *See Hoescht Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1578 (Fed. Cir. 1996) ("A technical term used in a patent document is interpreted as having the meaning that it would be given by a person experienced in the field of the invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning."). Intervet's construction replaces the word "vaccine" with the term "pharmaceutical composition." The latter term is more ambiguous, but in no respects more helpful.

Second, as discussed above, the prosecution history does not support construing "nucleic acid" as "naked DNA." In addition to the prosecution disclaimer argument, Intervet relies on Examples 2 and 5 in the specification, which both make reference to "naked DNA." But it is a basic tenet of claim construction that examples or embodiments described in the specification do not limit claim language, absent clear intent. *See, e.g., Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) ("Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope."). In fact, the examples Intervet relies on also disclose vaccines that do not use "naked DNA" as the antigen, but use a virus (specifically, recombinant baculoviruses) instead. In the detailed description section of the specification, an embodiment of the patented vaccine composition is also described which is comprised of a

[17]The Court notes that, in addition to the three terms given above, Intervet's construction replaces the word "comprising" with "containing." "Comprising" is a commonly used transition word in claim drafting with a well accepted meaning. "Containing" is not.

mixture of at least two of the following compounds: a nucleotide sequence, a polypeptide, a vector or viral particle, or a cell. ('023 patent, col 24 lines 35-48)

Finally, the Court finds that the term "encodes" needs no further construction. There is no justification for importing into this claim term Intervet's limitation requiring actual intracellular production of the immunogenic protein from naked DNA. The claim requires a gene that "encodes an immunogenic protein," but encoding a protein is different from producing the protein. Intervet's own expert made clear that DNA contains the information for making proteins, information used in a separate production process. (*See* Tech. Tutorial Tr., D.I. 186 at 42-43) ("DNA encodes for proteins and we could think about DNA as kind of a recipe for making something. . . . [T]hese are the recipes for making various components of the cell. And the most important component and the ones that are encoded by DNA are proteins. So DNA provides the information for making proteins.")

In sum, the Court finds that no construction of claim 1 is required.

C. "Amplifying Said Nucleic Acid"

Wyeth proposes that "amplifying said nucleic acid," a term appearing in claim 25 of the '594 patent, be construed to mean "increasing amount of said nucleic acid." (D.I. 160 at 19) Intervet proposes the construction "using a non-cell-based technique to increase the amount of a nucleic acid." (D.I. 159 at 15) The only dispute, therefore, is whether to include the limitation proposed by Intervet requiring a non-cell-based technique. The Court finds this limitation would be improper.

Claim 25 states:

> The method of claim 23, said method further including the step of amplifying said nucleic acid from a strain of PCVB prior to cloning said nucleic acid into said transfer vector.

Intervet argues that, based on this claim language, "amplifying" cannot encompass "cloning." (D.I. 159 at 16) ("[T]he two terms [amplifying and cloning] are not coextensive in meaning.") In further support of this point, Intervet refers to numerous excerpts from the specification where amplification and cloning are treated distinctly. (*See, e.g.,* '023 patent, col. 6 lines 34-45) ("[T]he present invention . . . concerns sequences which it has been possible to isolate, purify or partially purify, starting from separation methods . . . of genetic engineering such as amplification, cloning and subcloning, it being possible for the sequences of the invention to be carried by vectors.") However, Intervet's proposed construction would exclude not just cloning, but all cell-based amplification methods. An exclusion this broad is not supported by the claim or specification language Intervet cites.

The only support for excluding all cell-based techniques is the list of exemplary amplification methods provided in the specification, which includes only non-cell based techniques. This, however, is insufficient to justify the broad limitation Intervet proposes. *See Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1370 (Fed. Cir. 2008) ("[A]n applicant is not required to describe in the specification every conceivable and possible future embodiment of the invention."); *Phillips*, 415 F.3d at 1323 ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments."); *see also Liebel-Flarsheim* 358 F.3d at 906 (Fed. Cir. 2004) (requiring "a clear intention to limit the claim scope"). The Court refuses to exclude cell-based

amplification methods from the disputed term. Therefore, the Court construes the term "amplifying said nucleic acid" to mean "increasing the amount of said nucleic acid."

IV. CONCLUSION

For the reasons stated above, the disputed terms are construed as follows:

(a) The PCVB terms are construed to mean "a porcine circovirus having the genomic sequence of SEQ ID No. 15 or SEQ ID No. 19."

(b) Claim 1 of the '023 patent is given no construction.

(c) "Amplifying said nucleic acid" is construed to mean "increasing the amount of said nucleic acid."

An appropriate Order follows.